

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 10, 2022

WHITNEY ALEXANDER,

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No. 14-868V

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Petitioner,

*

Special Master Sanders

v.

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*

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

Dismissal; Insufficient Proof; Human

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Papillomavirus (“HPV” or “Gardasil”)

*

Vaccine; Premature Ovarian Failure/

Respondent.

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Primary Ovarian Insufficiency (“POF/POI”)

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Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.

Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

DISMISSAL DECISION¹

On September 18, 2014, Howard and Sharyn Alexander (“Mr. and Mrs. Alexander”) filed a petition for compensation on behalf of their then-minor daughter, Whitney Alexander (“Petitioner”), under the National Vaccine Injury Compensation Program² (“Vaccine Program” or “Program”). 42 U.S.C. § 300aa-10 to 34 (2012). Pet. at 1, ECF No. 1. The petition alleges that the human papillomavirus (“HPV” or “Gardasil”) vaccinations Petitioner received on February 25, 2008, April 28, 2008, and October 15, 2008, caused her to suffer from premature ovarian failure (“POF”). *Id.* The information in the record, however, does not show entitlement to an award under the Program.

On September 29, 2016, Respondent filed his Rule 4(c) report. Resp’t’s Report, ECF No. 34. Respondent argued that Petitioner had not satisfied her burden of proof under *Althen*, as “[t]here is nothing in the record offering a medical theory causally connecting the HPV vaccine to [P]etitioner’s condition and none of her treating doctors attributed her condition to the vaccine.”

¹ This Decision shall be posted on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the I agree that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 (“the Vaccine Act” or “Act”). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Id. at 4. Respondent also argued Petitioner had not established an appropriate temporal relationship between her vaccinations and injury. *Id.* Following the submission of several rounds of expert reports, this case was consolidated with several other POI matters to determine if any of the cases could proceed in light of the causation theory proposed in each of the petitioners' cases. *See, e.g.*, ECF Nos. 38, 41, 46–57, 59–72, 74, 76, 80–83, 86–89. On December 6, 2019, I held a status conference with the parties to discuss the presentation of the parties' arguments with respect to the viability of a causation theory pursuant to *Althen* prong one. *See* Min. Entry, docketed Dec. 6, 2019; *see also* No. 15-183V, ECF No. 80. Petitioner filed her brief on *Althen* prong one on June 18, 2020. No. 15-183V, ECF No. 86. Respondent submitted a response on September 22, 2020, and Petitioner filed a reply on November 20, 2020. No. 15-183V, ECF Nos. 88, 90.

I issued a ruling on *Althen* prong one on August 30, 2021, finding that the petitioners in the consolidated POI cases have presented a causation theory that, while not applicable to all of them, does survive *Althen* prong one under limited, specific circumstances. *See* Findings of Fact at 24, ECF No. 93. On December 14, 2021, I held a status conference in this matter to discuss whether preponderant evidence has been submitted showing that Petitioner suffers from POI with an autoimmune etiology so that she may proceed under *Althen* prongs two and three. Sched. Order at 1, ECF No. 95. Petitioner requested sixty days to file updated medical records, including antibody test results, and a status report indicating whether this case will proceed or be dismissed, and I granted her request. *See id.* Petitioner filed an unopposed motion for an extension of time to file the requested information on February 14, 2022. ECF No. 96. I stayed Petitioner's motion and ordered her to file a status report indicating whether the case will proceed with expert reports; and/or an explicit motion to supplement Petitioner's request for more time to file medical records containing additional objective testing. ECF No. 97. On March 15, 2022, Petitioner filed a medical record consisting of unofficial results from a recent antibody screening, which was positive for anti-ovarian antibodies. ECF No. 98. She also filed a supplemental motion for an extension of time to file the official record. ECF No. 99. Petitioner filed the official antibody test results on April 8, 2022. ECF Nos. 100–01.

I held a status conference with the parties on April 12, 2022. Min. Entry, docketed Apr. 12, 2022. During the conference, the parties discussed the relevancy of additional antibody testing, along with the additional factors set forth in my ruling on *Althen* prong one that will aid in my determination of vaccine-causation. *See* ECF No. 102. Petitioner again requested sixty days to file a status report or other filing identifying evidence regarding her basis to proceed with *Althen* prongs two and three consistent with the factors outlined in my ruling on *Althen* prong one. *Id.* I denied Petitioner's motion as moot and ordered her to file updated medical records containing antibody testing, if applicable, and a status report indicating that the case will not proceed or outlining the evidence she is relying on to continue with her claim. *See id.* I specifically told Petitioner to address the factors enumerated in my ruling on *Althen* prong one, aside from any recent positive antibody results if there have been years between such results and the onset of Petitioner's symptoms, and/or prior negative results. *Id.*

Following one unopposed extension of time, Petitioner filed a status report citing to evidence of an autoimmune etiology for her POF so that she could continue with her claim pursuant to *Althen* prongs two and three. ECF No. 106. She relied on medical records showing her irritable bowel syndrome, atrophic ovaries, low cortisol levels, weight gain, chronic fatigue, and her overall

symptom presentation. *Id.* at 1–3 (citing Pet’r’s Ex. 7 at 4, ECF No. 9-4). She also cited to her October 4, 2021 ovarian antibody testing, which showed positive results, but noted her prior testing was negative. *Id.* at 1 (citing Pet’r’s Ex. 115.2 at 2527, ECF No. 101-1; Pet’r’s Ex. 8 at 1, ECF No. 35-1). Petitioner submitted a piece of medical literature in support of her claim. ECF No. 105. I cautioned Petitioner that without more than recent positive antibody test results, Petitioner will likely be unsuccessful in establishing the applicability of the proposed biological mechanism. ECF No. 107. I ordered her to file an expert report on *Althen* prongs two and three within sixty days. *See id.*

On August 4, 2022, I held a status conference with the parties to discuss the ongoing critical deficiencies in the record concerning onset, as well as evidence of an autoimmune etiology in this case. *See* ECF Nos. 108–10; *see also* Min. Entry, docketed Aug. 4, 2022. Respondent agreed with my concerns regarding onset. ECF No. 110. I extended Petitioner’s deadline to file an expert report by thirty days. *See id.* Petitioner filed an expert report on September 21, 2022. ECF No. 111. Instead of filing a responsive expert report, Respondent filed a motion to dismiss Petitioner’s claim, arguing that her claim is time barred. ECF No. 112. I stayed Respondent’s deadline for filing an expert report and ordered Petitioner to file a response to Respondent’s motion by November 9, 2022. Non-PDF Order, docketed Oct. 27, 2022. Petitioner then filed an unopposed motion to voluntarily dismiss her claim on November 9, 2022, along with an unopposed motion to stay her deadline for filing a response to Respondent’s motion. ECF Nos. 114–15. Specifically, Petitioner indicated she has “reviewed her options for moving forward with her claim and wishes to file her case in the pending [litigation] directly against [the vaccine manufacturer.]” ECF No. 114 at 1. She requested a decision dismissing her claim and ending all rights in the Vaccine Program. *Id.*

To receive compensation under the Program, Petitioner must prove either (1) that she suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to the vaccination, or (2) that she suffered an injury that was actually caused by a vaccine. *See* §§ 13(a)(1)(A), 11(c)(1). An examination of the record did not uncover persuasive evidence that Petitioner suffered from a “Table Injury.” Further, the record does not contain persuasive evidence that Petitioner’s injuries were caused-in-fact by her HPV vaccinations.

Under the Act, petitioners may not be given a Program award based solely on their claims alone. Rather, the petition must be supported by medical records or the opinion of a competent physician. § 13(a)(1). In this case, the medical record is insufficient to prove Petitioner’s claim, and at this time, Petitioner has not filed sufficient supporting evidence. Therefore, this case must be **dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**³

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

³ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties’ joint filing of a notice renouncing the right to seek review.